

*Applicant: Phillips et al.  
Application Serial No. 09/735,363  
Amendment and Response to Non-Final Office Action  
Page 10 of 13*

### REMARKS

The above-identified patent application is directed to a composition, comprising a 3'-OH, 5'-OH synthetic phosphodiester nucleotide sequence and a method comprising administering the composition to an animal or a human. Prior to this amendment, Claims 1, 5, 10, 59, 61-62, and 65-67 were pending. By this amendment, applicants amend Claims 1 and 10, cancel Claim 5, and add new Claims 69-119. The amendments do not introduce any new matter. Upon entry of the amendments, Claims 1, 10, 59, 61-62, 65-67 and 69-119 will be pending.

#### *Telephone Interview*

Applicants thank the Examiner for the telephone interviews on November 9, 2005, and December 9, 2005.

#### *Allowable Subject Matter*

In the Office Action, the Examiner considers allowable combinations of the oligonucleotides recited in Claim 1 with a chemotherapeutic agent (the subject matter of Claim 5), an antimetabolite, an alkylating agent, or a hormone antagonist (the subject matter of Claim 10). Applicants amend Claim 1 to incorporate the subject matter of Claim 5, cancel Claim 5 as redundant, amend Claim 10 to correct its dependency, and add new independent Claim 69 based on Claims 1 and 10.

#### *Claim Rejections under 35 U.S.C. §102*

The Examiner rejects Claims 1, 61, 62, and 65-67 under 35 U.S.C. §102(b) as anticipated by random hexaoligonucleotides offered for sale by Boehringer Mannheim in 1997 and by Promega in 1978. The Examiner also rejects Claims 1 and 59 under 35 U.S.C.

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*Applicant: Phillips et al.  
Application Serial No. 09/735,363  
Amendment and Response to Non-Final Office Action  
Page 11 of 13*

§102(b) as anticipated by U.S. Patent No. 5,474,796 to Brennan. The Examiner asserts that U.S. Patent No. 5,474,796 teaches a trimeric oligonucleotide consisting of SEQ ID NO:8. In an effort to facilitate prosecution, applicants amend the claims to recite compositions comprising synthetic phosphodiester oligonucleotides and a chemotherapeutic agent. Claim 5 is cancelled as redundant, thereby rendering its rejection moot. Applicants respectfully assert that the amendments overcome the rejections of claims under 35 U.S.C. §102(b) and request withdrawal thereof.

Applicants amend Claim 1 to recite SEQ ID NOs:8-10, 25, 26, 41-43, 45 and 46 and add new Claim 69 to recite SEQ ID NOs 8-10, 25, 26, 41-43, 45. New dependent Claims 70-83 each recite one of SEQ ID NOs 8-10, 25, 26, 41-43, 45 and 46. By these amendments, applicants reintroduce into the claims synthetic phosphodiester oligonucleotides SEQ ID NOs 9, 42 and 46, which were deleted from Claim 1 by the previous amendment in an effort to facilitate prosecution. In the earlier Office Actions, the Examiner did not reject SEQ ID NOs 9, 42 and 46 when recited in Claims 5 and 10. Now, the Examiner considers Claims 5 and 10 allowable. Applicants request consideration and allowance of the amended claims based on the allowable claims and reciting SEQ ID NOs:8-10, 25, 26, 41-43, 45 and 46. In view of the foregoing, applicants respectfully request that Claims 1, 10, 59, 61-62, 65-67 and 69-83 be allowed.

#### **Double Patenting**

The Examiner provisionally rejects Claims 1, 61, 62, and 65-67 under the judicially created doctrine of obviousness type double patenting over Claims 1-6 of co-pending U.S. Patent Application Serial No. 09/879,558. Applicants respectfully request the Examiner to withdraw the rejection and to verify the serial number of the co-pending application. Applicants' U.S. Patent Application Serial No. 09/879,668 (not 09/879,558

9080026.2

*Applicant: Phillips et al.*  
*Application Serial No. 09/735,363*  
*Amendment and Response to Non-Final Office Action*  
*Page 12 of 13*

recited in the Office Action) is now abandoned. Applicants' co-pending U.S. Patent Application Serial No. 10/280,274 (Docket No. 02811-0242 (42368-279803)) claims priority to U.S. Patent Application Serial No. 09/879,668 (now abandoned).

### **Rejoinder**

If the composition of Claim 1 is found allowable, applicants request a rejoinder of the method of use claims reciting all the limitation of the composition claims in accordance with the provisions of MPEP §821.04. Applicants elected for prosecution composition claims Response to Restriction/Election Requirement filed March 4, 2002. Applicants add new method Claims 82-119 based on original Claims 11-42 and reciting all the limitations of currently amended Claim 1. Support for the new claims is found, for example, in original Claims 11-42 and throughout the specification, such as on p. 5, lines 25-30, p. 9, lines 20-24, p. 12, lines 6-14, p. 13, lines 16, 21, pp. 31-32, pp. 34-36, pp. 40-41, and pp. 50-54. In particular, Example 18 provides an example of potentiation by a synthetic phosphodiester oligonucleotide of antineoplastic properties of chemotherapeutic drugs. Synthetic phosphodiester oligonucleotides recited in the new claims, including the oligonucleotide discussed in the specification in Example 18, possess the unexpected and surprising ability to induce biological responses in cancer cells, such as inhibition of proliferation, induction of cell cycle arrest, induction of apoptosis, stimulation of cytokine production and activation of caspases (see pp. 5, lines 25-30, p. 9, lines 20-24). Applicants assert that, due to the common ability of the synthetic phosphodiester oligonucleotides recited in the claims to induce biological responses in cancer cells, the application is enabling with respect to methods of use of synthetic phosphodiester oligonucleotides in combination with a chemotherapeutic agent as recited in new Claims 84-119. Applicants request consideration and allowance of new Claims 82-119.

9080026.2

*Applicant: Phillips et al.  
Application Serial No. 09/735,363  
Amendment and Response to Non-Final Office Action  
Page 13 of 13*

### CONCLUSION

The foregoing is submitted as a full and complete response to the Office Action mailed August 3, 2005.

Applicants assert that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case that may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned agent at (404) 815-6102 or to Dr. John McDonald at (404) 745-2470 is respectfully solicited.

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Respectfully submitted,



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